



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/579,784 05/26/00 BASZCZYNSKI

C 5718-23B

029122 HM22/0921
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EXAMINER

ZARA, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/579,784

Applicant(s)

BASZCZYNSKI ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

File

Application/Control Number: 09/579,784.

Page 2

Art Unit: 1635

DETAILED ACTION

Claims 1-8 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon et al in view of Spencer et al, the combination in view of Perbal and Meisenberg et al and Gherzi et al.

The claims are drawn to a method of inactivating a target gene which had been introduced into a plant genome comprising first the transformation of a target plant cell with a transfer cassette comprising a promoter operably linked to a nucleotide sequence encoding the target gene

Art Unit: 1635

and then introducing into the target plant cell a chimeric RNA-DNA oligonucleotide which targets and implements a nucleotide conversion such as a frameshift, premature stop or mutation in the promoter region or coding region of the target gene whereby the expression of the target gene is interrupted, and which target gene includes a nucleotide sequence encoding a marker gene including a herbicide resistance gene.

Yoon et al teach the targeting and subsequent generation of nucleotide alterations in a target gene comprising the administration to a target cell of chimeric RNA-DNA oligonucleotides which recognize and implement a nucleotide conversion in the target gene (See the entire document, especially the abstract; figure 1 on page 2072; results on page 2073; figure 5 on page 2075).

Yoon et al do not teach the generation of a frameshift, premature stop or mutation in the promoter region of the target gene or in the coding region of the target gene which has been previously introduced into the genome of plant cells.

Spencer et al teach the generation of nucleotide mismatches or mutations in herbicide resistant genes of the genome of plants. (See especially the abstract; columns 3-6; columns 27-29; example 2 in columns 40-41; example 9 in columns 44-45).

Perbal teaches the oligonucleotide mediated introduction of mutations into a target nucleic acid sequence (See pages 685 and 686).

Art Unit: 1635

Meisenberg et al teach changes in the base sequences of nucleic acids which result in interruptions in the expression of the encoded polypeptide, which mutations include frame shift and premature termination of translation (See pages 168 and 169).

Gherzi et al teach the relationship between promoter function and operably linked reporter gene expression, whereby alterations or deletions of critical residues of a promoter region lead to interruption of the operably linked reporter gene expression (See especially figures 4 and 5 on page 3432).

It would have been obvious to one of ordinary skill in the art to utilize chimeric oligonucleotides for generating mutations or nucleotide mismatches into target sequences of previously disclosed nucleic acids, which chimeric oligonucleotides comprise a mismatch sequence flanked by sequences which are homologous to the target sequence, because such chimeric oligonucleotides have been disclosed previously by Yoon et al for the generation of mismatches to a target sequence in eukaryotic cells. It would have been obvious to incorporate a frameshift or premature termination mutation into a target gene using such chimeric oligonucleotides as described by Yoon et al because appropriate mismatches can be introduced instead of base substitutions using appropriate base changes or single nucleotide additions as taught previously by Parbal and Meisenberg et al. One of ordinary skill in the art would have been motivated to incorporate such changes into a target nucleic acid previously introduced into the genome of a target plant cell in order to revert the phenotype of the plant cell back to wildtype (i.e. by silencing a previously introduced gene which exerts an altered phenotype such

Art Unit: 1635

as the conversion, for agronomic reasons, of herbicide resistant to herbicide susceptible plants) whereby the expression of the target nucleic acid product is interrupted because gene silencing is obtained upon the introduction of such mutations into a target gene sequence. One of ordinary skill in the art would have expected that the introduction of a frame shift or a premature stop codon into the coding region of a target gene would interrupt the normal expression of that target gene as taught previously by Meisenberg et al. One of ordinary skill in the art would have expected that the significant alteration or removal of critical sequences necessary for the expression of operably linked coding sequences on a previously characterized promoter would interrupt the normal expression of the operably linked coding sequence because such approaches had been routinely applied to promoter characterization studies, whereby upon promoter disruption due to deletion or critical sequence alteration there is an interruption of the operably linked reporter gene, as taught previously by many including Gherzi et al.

Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1635

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

September 13, 2001


ANDREW WANG
PRIMARY EXAMINER